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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/682,460	10/08/2003	Kenneth E. Kadziauskas	27564	1644

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EXAMINER	
HAND, MELANIE JO	
ART UNIT	**PAPER NUMBER**
3761	

DATE MAILED: 12/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	**Application No.** 10/682,460	**Applicant(s)** KADZIAUSKAS ET AL.	
	Examiner Melanie J. Hand	**Art Unit** 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 12 September 2006.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-44 is/are pending in the application.

4a) Of the above claim(s) 6,8,12,13,19,21,25-28,34,36 and 40 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-5, 7, 9-11, 14-18, 20, 22-24, 29-33, 35, 37-39, and 41-44 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 01 August 2005 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of species (i), species I, group I, claims 1-5, 7, 9-11, 14-18, 20, 22-24, 29-33, 35, 37-39, and 41-44 in the reply filed on September 12, 2006 is acknowledged.

Claims 6,8,12,13,19,21,25-28, 34, 36 and 40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on September 12, 2006.

Claim Objections

Claim 43 is objected to because of the following informalities: the phrase "the tubular member" lacks proper antecedent basis. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11, 24 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims set forth the limitation of expandable walls that are relatively thin and a sheath that is relatively thick. Although it is understood from the disclosure that the comparison regarding thickness is between the expandable member and the sheath (e.g. that the expandable member is thin relative to the sheath), it is not clear to one of ordinary skill in the art what the resulting definitions of thin and thick would be.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 7, 9, 14-18, 20, 22, 29-33, 35, 37, and 41-44 are rejected under 35 U.S.C. 102(e) as being anticipated by Baerveldt et al (U.S. Patent No. 6,979,328).

With respect to **claim 1:** Baerveldt teaches an infusion source for ocular surgery having a needle 1400 with at least an irrigation lumen 1622 comprising: a fluid supply 1480; an irrigation line interconnecting said fluid supply 1480 and said irrigation lumen 1622 (Fig. 13); and a tubular member 1410 disposed in fluid communication with said irrigation line and said irrigation lumen 1622, said tubular member 1410 having an expandable wall for enabling accumulation of fluid within said tubular member 1410, during occlusion of an aspiration lumen (lumen 1622 when said tubular member 1410 is expanding for permitting removal of material from a surgical site, i.e. when lumen 1622 is not being used for irrigation) and enhanced flow of fluid into said irrigation lumen 1622 upon clearing of the occlusion, i.e. when expansion of member 1410, and thus aspiration of material, stops. (Col. 11, lines 18-26, 34-37, 57-61)

With respect to **claim 2:** Tubular member 1410 is disposed proximate a handpiece 1405 effective for use in a phacoemulsification procedure. (Col. 11, lines 39-41)

With respect to **claim 3:** Tubular member 1410 is disposed in parallel fluid communication with said irrigation line and irrigation lumen 1622 (Figs. 14,16) (Col. 11, lines 18-21,31-35)

With respect to **claim 4:** The tubular member walls are formed from an elastic material. (Col. 9, lines 30-36)

With respect to **claim 5:** Tubular member 1410 comprises a sheath disposed around the expandable wall. (Col. 10, lines 58-63)

With respect to **claim 7:** Baerveldt teaches that the sheath is comprised of electrically insulating material, substantially all of which materials (e.g. rubber, polyurethane foam) are flexible. (Col. 10, lines 58-62)

With respect to **claim 9:** The sheath and expandable wall are integrally molded. (Col. 9, lines 57,58, Col. 10, lines 58-62)

With respect to **claim 14:** Baerveldt teaches an infusion source for ocular surgery, said infusion source comprising: a handpiece having a needle with an irrigation lumen 2222 and an aspiration lumen 2224; a fluid supply in the form of an irrigation pump; an irrigation line interconnecting said fluid supply and said irrigation lumen 2222; and a tubular member 2100 disposed in fluid communication with said irrigation line and said irrigation lumen 2222, said tubular member 2100 having an expandable wall for enabling accumulation of fluid within said tubular member during occlusion of said aspiration lumen and enhanced flow of fluid into said irrigation lumen upon clearing of the occlusion. (Figs. 21,22)(Col. 11, lines 36-62, Col. 15, lines 4-20)

With respect to **claim 15:** Tubular member 2100 is disposed proximate the handpiece. (Fig. 21)

With respect to **claim 16:** Tubular member 2100 is disposed in parallel fluid communication with said irrigation line and said irrigation lumen 2222. (Figs. 21,22)(Col. 15, lines 4-20)

With respect to **claim 17:** The tubular member walls are formed from an elastic material. (Col. 9, lines 30-36)

With respect to **claim 18:** The tubular member 2100 comprises a sheath 2146 disposed around the expandable wall. (Col. 14, lines 46-53)

With respect to **claim 20:** Baerveldt teaches sheaths comprised of electrically conductive material, substantially all of which materials (e.g. rubber, polyurethane foam) are flexible. (Col. 10, lines 58-62)

With respect to **claim 22:** The sheath 2146 and expandable wall are integrally molded. (Col. 14, lines 49,50)

With respect to **claim 29:** Baerveldt teaches an ocular surgical system for performing ocular surgery on an eye, comprising: a handpiece driven by a controller through a power line; an irrigation lumen 2222 and an aspiration lumen 2224, said infusion source comprising: a fluid supply in the form of an irrigation pump; an irrigation line interconnecting said fluid supply and said irrigation lumen 2222; and a tubular member 2100 disposed in fluid communication with said irrigation line and said irrigation lumen 2222, said tubular member 2100 having an expandable wall for enabling accumulation of fluid within said tubular member, during occlusion of said aspiration lumen 2224, and enhanced flow of fluid into said irrigation lumen upon clearing of the occlusion. (Figs. 21,22)(Col. 11, lines 36-62, Col. 15, lines 4-20)

With respect to **claim 30:** Tubular member 2100 is disposed proximate the handpiece. (Fig. 21)

With respect to **claim 31:** Tubular member 2100 is disposed in parallel fluid communication with said irrigation line and said irrigation lumen 2222. (Figs. 21,22)(Col. 15, lines 4-20)

With respect to **claim 32:** The tubular member walls are formed from an elastic material. (Col. 9, lines 30-36)

With respect to **claim 33:** The tubular member 2100 comprises a sheath 2146 disposed around the expandable wall. (Col. 14, lines 46-53)

With respect to **claim 35:** Baerveldt teaches sheaths, including sheath 2146, that are comprised of electrically conductive material, substantially all of which materials (e.g. rubber, polyurethane foam) are flexible. (Col. 10, lines 58-62)

With respect to **claim 41:** An accumulator for an ocular surgical handpiece, comprising: a tubular portion 2100 comprising an expandable wall; and a sheath 2146 disposed around the expandable wall; the accumulator configured to enable accumulation of fluid within the tubular member during occlusion of an aspiration lumen and to enhance the flow of fluid into an ocular surgical handpiece upon clearing of the occlusion. (Figs. 21,22)(Col. 11, lines 36-62, Col. 15, lines 4-20)

With respect to **claim 42:** The sheath 2146 and the expandable wall are integrally molded.(Col. 14, lines 49,50)

With respect to **claim 43:** Baerveldt teaches an infusion source for an ocular surgical handpiece, comprising: an irrigation fluid supply in the form of a pump; an irrigation line connected to the irrigation fluid supply for supplying fluid to an ocular surgical handpiece; an accumulator 2100 in fluid communication with the irrigation line, comprising: an expandable wall for enabling accumulation of fluid; and a sheath 2146 disposed around the expandable wall; the accumulator 2100 configured to provide accumulation of fluid within a tubular member during occlusion of an aspiration lumen and to enhance the flow of fluid into the ocular surgical handpiece upon clearing of the occlusion. (Figs. 21,22)(Col. 11, lines 36-62, Col. 15, lines 4-20)

With respect to **claim 44:** The sheath 2146 and the expandable wall are integrally molded. (Col. 14, lines 49,50)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 10, 11, 23, 24, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baerveldt in view of Sussman et al (U.S. Patent No. 6,589,201)

With respect to **claims 10,22,38:** Baerveldt teaches that tubular member 2100 has expandable walls and a sheath 2146 but does not teach a plurality of expandable walls in spaced apart relation within a sheath. Sussman teaches a handpiece tip having coaxial irrigation and aspiration lumens that define an annular space therebetween. Surgical fluid is channeled through these lumens and expands within these tubes, thus expanding the tubes themselves. Sussman teaches that the fluid is pumped through the handpiece tip to the surgical site, thus when the irrigation lumen expands, occlusion of the aspiration lumen will occur. Sussman teaches that the tip allows internal heating of the surgical fluid to the desired temperature without the need for a separate heating device. Since Baerveldt teaches that the sonic energy applied to the said handpiece also provides heat to a fluid in the irrigation lumen of said handpiece, it would be obvious to one of ordinary skill in the art to substitute the handpiece tip taught by Baerveldt with the handpiece taught by Sussman so as to effect a plurality of expanding walls with a spaced apart relation to provide heat to a surgical fluid as taught by Sussman without the need for a separate heating device. ('201, Col. 5, lines 9-18, Col. 2, lines 34-36)

With respect to **claim 11:** Sussman does not explicitly teach flexible elastic expanding walls defined by the walls of irrigation and aspiration tubes 115, but teaches that flexible tubes are known in the art, therefore it would be obvious to one of ordinary skill in the art to use flexible elastic material for the expanding walls. ('201, Col. 1, lines 33-42)

With respect to **claim 24,39:** Baerveldt teaches a handpiece effective for use during a phacoemulsification procedure, but does not teach a plurality of expandable walls. Sussman teaches a handpiece tip having coaxial irrigation and aspiration lumens that define an annular space therebetween. Surgical fluid is channeled through these lumens and expands within these tubes, thus expanding the tubes themselves. Sussman teaches that the tubes defining the expanding walls are comprised of flexible elastic material. Sussman teaches that the fluid is pumped through the handpiece tip to the surgical site, thus when the irrigation lumen expands, occlusion of the aspiration lumen will occur. Sussman teaches that the tip allows internal heating of the surgical fluid to the desired temperature without the need for a separate heating device. Since Baerveldt teaches that the sonic energy applied to the said handpiece also provides heat to a fluid in the irrigation lumen of said handpiece, it would be obvious to one of ordinary skill in the art to substitute the handpiece tip taught by Baerveldt with the handpiece taught by Sussman so as to effect a plurality of expanding walls with a spaced apart relation to provide heat to a surgical fluid as taught by Sussman without the need for a separate heating device. The combined teaching of Baerveldt and Sussman teaches expandable walls and a sheath formed from an elastic material. Baerveldt teaches that the sheath is thick enough to be an effective electrical insulator, therefore the combined teaching of Baerveldt and Sussman teaches expandable walls being relatively thin, said sheath being relatively thick.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie J. Hand whose telephone number is 571-272-6464. The examiner can normally be reached on Monday-Thursday 8:00-5:30, alt. Fridays 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Melanie J Hand
Examiner
Art Unit 3761

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

MJH